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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,239	11/07/2005	Jean Benard	03715.0146	1634

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,239	BENARD, JEAN	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4 and 25* is/are rejected.

7)☐ Claim(s) *4-24 and 26-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/7/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-30 are pending and examined on the merits.

Claim Objections

Claims 4-24 and 26-30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 4-24 and 26-30 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 is dependent upon the identity of a genus of cell cultures "derived from" IGR-OV-22-AS and IGR-BR-11-NS. When given the broadest reasonable interpretation, cultures "derived from" said recited cultures encompass cultures having undergone mutation and/or alteration of culture phenotype. The description of two cell culture lines, IGR-OV-22-AS and IGR-BR-11-NS, fails to adequately describe this genus because said genus tolerates members which differ in both genotype and phenotype from IGR-OV-22-AS and IGR-BR-11-NS. One of skill in the art would reasonably conclude that applicant was not in possession of a genus of cell cultures "derived from" IGR-OV-22-AS and IGR-BR-11-NS, and therefore not in possession of the method of claim 25 which is dependent upon said genus of cell cultures.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 25 requires the deposited cell lines of IGR-OV-22 and IGR-BR-11-NS but applicant has failed to satisfy all the terms of the deposit requirement. There is no reasonable expectation that one of skill in the art could isolate cell lines identical to those claimed as the origin of the material depends upon mutational event within a tumor in a cancer patient and therefore outside of the influence of one of skill in the art.

If deposits are made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney or record who has the authority and control over the conditions of deposit over his/her signature or registration number stating that the deposit has been accepted by an International Depository authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed from the depository as required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit. If deposits are made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the deposited cell lines are the same as those described in the specification as filed and were in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re: Lundak, 773 F. 2d.1216, 227 USPQ 90 (CAFC 1985) and 37 CRF 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Bernard et al (Cancer Research, 1985, Vol. 45, pp. 4970-4979).

Claim 25 is drawn in part to a method of selecting a compound capable of inhibiting the growth and/or proliferation of tumor cells comprising a) bringing said compound into contact with a IGR-OV-22-AS tumor cell line, and selecting said compound if it is capable of inhibiting the growth and/or proliferation of said tumor cells.

Bernard et al disclose a method of selecting a compound capable of inhibiting the growth and or proliferation of an IGR0V1 tumor cell line (page 4972, second column, under the heading of

"Drug Sensitivity of IGROV1 Cells" and page 4973, Chart 2). The reference does not specifically disclose that the IGROV1 Cell line is the same as cell line "derived from" the IGR-OV-22 cell line of the instant claim However, the claimed method appears to utilize the same cell line as the method of the prior art in terms of origin of the primary cells. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Nederman et al (Cancer Research, 1984, Vol. 44, pp. 3090-3097) as evidenced by the abstract of Heldin et al (Thryoidology, 1991, Vol. 3, pp. 127-131).

Claim 1 is drawn to a method for preparing an isolated extracellular matrix secreted by tumor cells of animal origin including human, comprising culturing said tumor cells on a support under conditions that allow said tumor cells to proliferate and to secrete an ECM and recovering said ECM thus formed, from which said tumor cells have been removed. Claim 2 embodies the method of claim 1, wherein tumor cells are lysed before the ECM is recovered. Claim 3 embodies the method of claim 1 or 2 wherein the tumor cells are epitheliomatous cells.

Nederman et al disclose a method of isolating extracellular matrix formed by human glioma cell line and a human thyroid tumor cell line in culture (page 3090, second column under the heading of "Cells") which fulfills the specific embodiment of culturing on a support. The abstract of Heldin et a provides evidence that the hTH-7 cell line is a anaplastic thyroid carcinoma cell line which provides evidence that the cells are epitheliomatous cells. Nederman et al disclose the extraction of the ECM by extraction with deoycholate followed by hypotonic buffer (page 3090, second column, lines 1-3 of the paragraph entitled "Histology and Extraction Procedures"). It is noted that the hypotonic buffer would provide for residual tumor cell lysis which is substantiated on page 3091, second column, second paragraph under "Results").

Claims 1-3 and 25 are rejected. Claims 4-24 and 26-30 are withdrawn from consideration..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner
Art Unit 1643